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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,604	03/08/2004	Richard S. Bein	355492-2971	1765

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
10/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,604	BEIN ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Arguments filed on 08/06/2010.

- Claim 25 has been amended.
- Claims 1-24, 26 and 30 have been cancelled.
- Claims 25 and 27-29 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-29 rejected under 35 U.S.C. 112, second paragraph, **are withdrawn** in view of amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 27-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (US 2002/0090339) in view of Paterson et al (US 2004/0224864) or Porte et al (US 2004/0197302) **are maintained** for reasons of record in the previous office action filed on 07/20/2009, 12/24/2009 and 04/09/2010.

Applicant arguments filed on 08/06/2010 have been fully considered but they are not persuasive.

Applicant argues that none of the cited references teach or suggest a contrast agent concentration of from about 45 to no more than 60 weight percent.

This argument is not persuasive since, it is noted that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Further both Paterson et al on (0138 and 0213) and Porte et al on (0053 and 0069) is suggestive of water-soluble biocompatible contrast agents from about 20 to about 55 weight percent of composition.

Claims 25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (US 2002/0090339) in view of Dure-Smith et al (US 3,937,800).

Claims are drawn to a composition consisting essentially of up to 40%of ethylene vinyl alcohol copolymer; dimethylsulfoxide; and from about 45 to no more than 60

weight percent of tantalum contrast agent having an average particle size of about 5 microns or less; wherein the ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent is from 0.077 to 0.90.

Whalen discloses a composition comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition (abstract and 0032-0035). The preferred biocompatible polymers include cellulose acetates, ethylene vinyl alcohol copolymers and mixtures thereof (0060). The water insoluble contrast agents include tantalum, tantalum oxide, and barium sulfate of particle size of about 10 microns or less and more preferably at from about 1 to about 5 microns (0067 and 0078). The biocompatible solvent includes ethyl lactate, dimethylsulfoxide, ethanol, acetone and the like (see 0069). Additional disclosure includes that sufficient amounts of the contrast agent can be added to the biocompatible solvent to achieve the effective concentration for the complete composition (0077).

Whalen fails to teach specific concentration of tantalum contrast agent from about 45 to no more than 60 weight percent in the composition.

Dure-Smith teaches an X-ray contrast media composition containing tantalum metal ranges from about 20% to about 70% by weight (col. 3 lines 3-6 and col. 6 lines 10-15). The tantalum metal has an average particle diameter in the range from about

0.5 microns to 30 microns (col. 2 lines 44-46). Additional disclosure includes that physiologically and pharmaceutically acceptable amount of X-ray opaque material (tantalum) when combined with common contrast media ingredients of a non-opaque nature (suspending agent, viscosity builder, surfactant, etc.) will give a smooth, flowable, evenly dispersed contrast media.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a water-insoluble, biocompatible contrast agent from 45 to no more than 60 weight percent into Whalen's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because Dure-Smith teaches that compositions containing tantalum metal which can be conveniently and safely administered to the lungs in order to obtain sharp, clear X-ray films of the bronchial tree (col. 2 lines 25-30). In addition, tantalum metal is highly compatible with most common contrast media ingredients and composition comprising higher concentration of water-insoluble, biocompatible contrast agent can increase the degree of visualizing effect capable of being monitored during injection into a mammalian subject and reasonably would have expected success because Dure-Smith's teaches that finely divided tantalum metal is completely inert and is not toxic to body tissue and when incorporated in to composition in physiologically and pharmaceutically acceptable amounts will give a smooth, flowable, evenly dispersed contrast media for obtaining x-ray films of sufficient clarity and detail for use in bronchography.

Furthermore, the optimization of the pharmaceutical formulation with ingredients well known in the pharmaceutical art is considered well within the competence level of an ordinary skilled artisan in the pharmaceutical sciences, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980)

Double Patenting

Claims 25-30 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims of 1-6 of US Patent No. 5,667,767 ('767)and claims 1-8 and 16-23 of US Patent No. 5,695,480 ('480) **are maintained** for reasons of record in the previous office action filed on 04/09/2010.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./ /Jake M. Vu/

Examiner, Art Unit 1618 Primary Examiner, Art Unit 1618